CLAIMS

What is claimed is:

1. A tissue severing device, comprising:

a guide comprising two co-linear, co-extensive guide lumens longitudinally extending from a proximal region to a distal terminus along a guide axis, wherein the guide lumens have co-extensive distal segments terminating in distal tips and the angle of each distal segment in relation to the guide axis is generally fixed;

a cutting tool contained within the guide and capable of forming a cutting loop extending from the distal tips of the two guide lumens, said cutting loop having a loop extension axis defined by the direction in which the cutting loop extends; and

an extension means for controlling the degree to which the cutting loop extends from the guide.

2. The device of claim 1, wherein said distal tips are at a generally fixed distance therebetween such that the width of the cutting loop when the cutting loop is extended is generally fixed.

3. The device of claim 1, wherein the angles between each distal segment and the guide axis are one of the same and different.

4. The device of claim 1, further comprising a width adjuster for selectively moving the distal tips of the distal segments relative to each other to thereby selectively adjust the width of the cutting loop.

5. The device of claim 4, wherein said width adjuster moves the distal tips of the distal segments and varies the distance between the distal tips by rotating at least one of the guide lumens.

6. The device of claim 4, further comprising a handle at the proximal region of the guide, said handle comprising the extension means and the width adjuster.

7. The device of claim 1, wherein the cutting tool comprises an electrically conductive material.

8. The device of claim 7, wherein the electrically conductive material is a metallic material selected from the group consisting of a metal, a metal alloy, a metal laminate, and a metal composite.

9. The device of claim 8, wherein the metallic material is one of titanium, titanium alloy, nickel-titanium alloy, nickel-chromium, and iron-chromium alloy.

10. The device of claim 7, wherein the cutting tool is operatively coupled to an energy source.

11. The device of claim 10, wherein the energy source is one of a heat source, a radio frequency energy source, and an ultrasonic energy source.

12. The device of claim 10, wherein the energy source is a radio frequency energy source and the cutting tool is a component of a monopolar or a bipolar system.

13. The device of claim 1, wherein the cutting tool has a predetermined cross-sectional shape.

14. The device of claim 1, wherein the cutting tool has a cutting edge and a trailing edge.

15. The device of claim 14, wherein the cutting edge is at least one of sharpened and serrated.

16. The device of claim 14, further comprising a vibration-providing means for inducing mechanical vibration of the cutting tool.

17. The device of claim 1, wherein the guide lumens comprise an electrically insulating material.

18. The device of claim 1, further comprising a tissue collector for collecting and removing tissue severed by the cutting tool.

19. The device of claim 18, further comprising a tissue collector controller for controlling said tissue collector.

20. The device of claim 18, wherein the tissue collector is adapted to collect tissue at least one of as the tissue is being severed and after the tissue is severed.

21. The device of claim 18, wherein the tissue collector comprises a tissue collection bag, said collection bag being one of directly and indirectly attached to the distal terminus of the guide.

22. The device of claim 21, further comprising means for opening and closing the tissue collection bag.

23. The device of claim 21, wherein said tissue collection bag is attached to said cutting tool whereby increasing and decreasing the size of said cutting loop opens and closes said tissue collection bag, respectively.

24. The device of claim 21, wherein said tissue collection bag is electrically insulated from said cutting tool.

25. The device of claim 21, wherein said collection bag is deployable and adjustable independent of said cutting tool and wherein said tissue collector further comprises a collection loop adapted to be selectively opened and closed.

26. The device of claim 21, wherein said tissue collector further comprises a tissue collection loop adapted to be selectively opened and closed and two tissue collection lumens having collection distal tips from which said collection loop extends, said tissue collection bag being attached to said tissue collection loop.

27. The device of claim 26, wherein said collection loop is aligned with said cutting loop.

28. The device of claim 21, wherein the collection bag comprises an impermeable material.

29. The device of claim 28, wherein the impermeable material is selected from the group consisting of polyethylene, polypropylene, polybutylene, polyamide, polyimide, polyester, polyvinyl chloride, polyvinyl fluoride, polyvinylidene fluoride, polycarbonate, and polytetrafluoroethylene.

30. The device of claim 1, further comprising a tissue marker, said tissue marker configured to mark tissue severed by the cutting tool.

31. The device of claim 30, wherein the tissue marker is in electrical communication with an external energy source.

32. The device of claim 31, wherein the external energy source is a radio frequency energy source.

33. The device of claim 32, wherein the tissue marker comprises means for charring or creating blackened marks on the surface of the severed tissue.

34. The device of claim 33, wherein the tissue marker comprises marking segments extending from a trailing edge of said cutting loop.

35. The device of claim 34, wherein the marking segments comprise a metallic material.

36. The device of claim 34, wherein the marking segments are asymmetrically arranged along the trailing edge of the cutting loop.

37. The device of claim 34, wherein the marking segments comprise electrically conductive wires.

38. The device of claim 37, wherein at least some of the electrically conductive wires are interwoven to create a pattern asymmetrically arranged along the trailing edge of the cutting loop.

39. The device of claim 34, wherein the marking segments comprise extensions of the cutting loop asymmetrically arranged thereon.

40. The device of claim 30, wherein the tissue marker comprises a dye for staining the severed tissue.

41. The device of claim 40, wherein the dye is located on a plurality of regions on the interior surface of one of a collection bag and the cutting loop.

42. The device of claim 41, wherein the individual regions of dye are arranged in an asymmetric pattern on the interior surface of one of the collection bag and the cutting loop.

43. The device of claim 40, wherein the collection bag comprises an opening, said opening containing the dye in individual regions thereon.

44. The device of claim 40, wherein said dye is of at least two different colors.

45. The device of claim 1, wherein the guide lumens are affixed to each other.

46. The device of claim 1, wherein the guide lumens are housed in a tubular shaft, said tubular shaft having a distal end and a proximal end.

47. The device of claim 46, wherein the tubular shaft further includes at least one accessory lumen.

48. The device of claim 47, further comprising a tissue collector for collecting and removing tissue severed by the cutting tool, said tissue collector being contained in one of the at least one accessory lumens.

49. The device of claim 48, wherein the tubular shaft has at least one opening at the distal end and wherein the tissue collector is adapted to extend from and retract into the tubular shaft through one of the at least one opening at the distal end.

50. The device of claim 47, wherein the at least one accessory lumen comprises at least one transport lumen that allows a material to be transported therethrough to the distal end.

51. The device of claim 50, further comprising a source of gas, liquid or a combination thereof in fluid communication with the at least one accessory lumen.

52. The device of claim 50, wherein the at least one accessory lumen additionally comprises at least one vacuum lumen operatively connected to a vacuum source.

53. The device of claim 47, wherein the at least one accessory lumen comprises at least one vacuum lumen operatively connected to a vacuum source.

54. The device of claim 46, further comprising a tissue penetration means for facilitating tissue penetration, said tissue penetration means being attached to said distal end of said tubular shaft.

55. The device of claim 54, wherein the tissue penetration means comprises at least one of a sharpened edge and a sharpened tip.

56. The device of claim 54, wherein the tissue penetration means is operatively coupled to an external energy source.

57. The device of claim 56, wherein the external energy source is one of a radio frequency energy source and an ultrasonic energy source.

58. The device of claim 57, wherein the external energy source is the radio frequency energy source and the tissue penetration means is a component of a monopolar or a bipolar system.

59. The device of claim 46, wherein the tubular shaft has a primary window near the distal end.

60. The device of claim 59, wherein the distal tips of the guide lumens are aligned with the primary window and the cutting tool is adapted to extend and retract therethrough.

61. The device of claim 60, further comprising a tissue collector adapted to collect and remove severed tissue, said tissue collector being contained in the primary window and extendible therefrom.

62. The device of claim 61, wherein said tissue collector comprises a tissue collection loop, a tissue collection bag attached thereto, and two tissue collection lumens having collection distal tips from which said tissue collection loop extends, said tissue collection loop adapted to be selectively opened and closed.

63. The device of claim 59, wherein said tubular shaft comprises a sliding cover for selectively uncovering and covering said primary window.

64. The device of claim 63, further comprising a cover controller for selectively controlling the position of the sliding cover with respect to the primary window.

65. The device of claim 59, wherein the tubular shaft has an additional window near the distal end of the tubular shaft adjacent to the primary window.

66. The device of claim 65, further comprising a tissue collector for collecting and removing tissue severed by the cutting tool, said tissue collector being contained in the additional window.

67. The device of claim 66, wherein the tissue collector is extendible and retractable through said additional window.

68. The device of claim 67, wherein said tubular shaft comprises a sliding cover for selectively uncovering and covering at least one of said primary window and said additional window.

69. The device of claim 68, further comprising a cover controller for selectively controlling the position of the cover with respect to at least one of the primary window and the additional window.

70. The device of claim 46, wherein the tubular shaft has at least one opening at the distal end and wherein the guide lumens are adapted to extend from and retract into the tubular shaft through at least one of the at least one opening at the distal end.

71. The device of claim 70, further comprising an extension-retraction controller adapted to extend and retract the guide lumens with respect the tubular shaft.

72. A tissue severing device, comprising:

a guide comprising two co-linear, co-extensive guide lumens longitudinally extending from a proximal region to a distal terminus along a guide axis, wherein the guide lumens have co-extensive distal segments terminating in distal tips and deformable regions immediately proximal to the distal segments, said deformable regions facilitate in changing the direction of the distal segments with respect to the guide axis;

a cutting tool contained within the guide and capable of forming a cutting loop extending from the distal tips of the two guide lumens, said cutting loop having a loop extension axis defined by the direction in which the cutting loop extends;

an extension means for controlling the degree to which the cutting loop extends from the guide; and

a distal segment positioning means for varying the direction of each distal segment with respect to the guide axis to thereby adjust the angle between the loop extension axis and the guide axis and selectively position the cutting loop with respect to the guide axis.

73. The device of claim 72, further comprising a width adjuster to facilitate in selectively moving the distal tips of the distal segments relative to each other to thereby selectively adjust the width of the cutting loop.

74. The device of claim 73, wherein the width adjuster moves the distal tips of the distal segments and varies the distance between the distal tips by rotating at least one of the guide lumens.

75. The device of claim 72, wherein said distal tips are at a generally fixed distance therebetween.

76. The device of claim 72, wherein said distal segment positioning means comprises retraction cables, each attached to one of said distal segments, whereby selective tightening and relaxing of said retraction cables adjusts the direction of the distal segments with respect to the guide axis.

77. The device of claim 76, wherein selective tightening and relaxing of said retraction cables further positions the cutting loop when extended so as to adjust the angle between the loop extension axis and the guide axis to thereby reposition the cutting loop with respect to the guide axis.

78. The device of claim 76, wherein said retraction cables are at least partially and movably disposed within said guide lumens.

79. The device of claim 72, wherein said deformable regions comprise a shape-memory material.

80. A tissue severing device, comprising:

a guide comprising a guide lumen longitudinally extending from a proximal region to a distal terminus along a guide axis, said guide lumen having a distal segment terminating in a distal tip;

a cutting tool having a fixed end and is at least partially contained within the guide lumen when in a stored configuration and extendible from the distal tip thereof, wherein extension of the cutting tool from the guide lumen forms a cutting loop having a loop extension axis defined by the direction in which the cutting loop extends;

an extension means for controlling the degree to which the cutting loop extends from the guide lumen; and

a width adjuster for selectively adjust the width of the cutting loop.

81. The device of claim 80, wherein the direction of the distal segment with respect to the guide axis is one of variable and generally fixed.

82. The device of claim 80, wherein the direction of the distal segment with respect to the guide axis is variable and wherein said guide lumen comprises a deformable region immediately proximal to the distal segment to facilitate changing the direction of the distal segment with respect to the guide axis, the device further comprising a distal segment positioning means for varying the direction of the distal segment with respect to the guide axis.

83. The device of claim 82, wherein, when said cutting loop is extended from the distal tip of the guide lumen, said distal segment positioning means is configured to adjust the angle between the loop extension axis and the guide axis to thereby selectively position the cutting loop with respect to the guide axis.

84. The device of claim 82, wherein said distal segment positioning means comprises a retraction cable attached to said distal segment, whereby selective tightening and relaxing of said retraction cable adjusts the direction of the distal segment with respect to the guide axis.

85. The device of claim 84, wherein, when the cutting loop is extended, selective tightening and relaxing of said retraction cables further positions the cutting loop so as to adjust the angle between the loop extension axis and the guide axis to thereby selectively position the cutting loop with respect to the guide axis.

86. The device of claim 84, wherein said retraction cables are at least partially and movably disposed within said guide lumens.

87. The device of claim 82, wherein said deformable region comprises a shape-memory material.

88. The device of claim 80, wherein the fixed end of the cutting tool is attached to an external region of the guide.

89. The device of claim 80, further comprising a tubular shaft housing said guide lumen and wherein the fixed end of the cutting tool is attached to the tubular shaft.

90. The device of claim 80, wherein the width adjuster is operable by rotating the guide lumen about the guide axis and with respect to the fixed end.

91. A method for excising at least a part of a lobe from within a human patient's breast, comprising the steps of:

locating the lobe that is to be excised within in the breast; and

excising at least a part of the lobe utilizing a tissue severing device.

92. The method of claim 91, further comprising:

finding a lesion within a lobe;

evaluating the size of the lesion within the lobe;

identifying any extensions of the lesion and any additional lesions within the lobe; and

determining from said finding, evaluating, and identifying whether to excise at least a part of the lobe, the entire lobe or the entire lobe plus additional surrounding tissue in said excising in order to remove the lesion or lesions from the breast.

93. The method of claim 92, wherein said identifying comprises identifying any extensions of the lesion and any additional lesions within a duct system of the lobe.

94. The method of claim 92, wherein at least one of said finding, evaluating, identifying, and employing is carried out using a radiological imaging modality.

95. The method of claim 94, wherein the radiological imaging modality comprises at least one of ultrasound imaging, radial ultrasound scanning, axial ductal ultrasound scanning, three-dimensional ultrasound imaging, magnetic resonance imaging, three-dimensional magnetic resonance imaging, mammography, digital mammography, and stereotactic mammography.

96. A method for removing a lesion from a patient, comprising:

locating the lesion to be severed and removed from within a selected region of the patient;

inserting a guide through an incision, the guide comprising two co-linear, co-extensive guide lumens longitudinally extending from a proximal region to a distal terminus along a guide axis, wherein the guide lumens have co-extensive distal segments terminating in distal tips and the angle of each distal segment relative to the guide axis is generally fixed;

advancing the guide into the selected region;

extending a cutting tool contained within the guide from the distal tips of the two guide lumens to form a cutting loop, said cutting loop having a loop extension axis defined by the direction in which the cutting loop extends; and

moving the cutting loop using the guide along the guide axis to sever tissue containing the lesion from the selected region.

97. The method of claim 96, further comprising removing the severed tissue from the selected region.

98. The method of claim 96, wherein the selected region is located within a breast of a human patient.

99. The method of claim 98, wherein the incision is located at or near the periareolar region of the breast.

100. The method of claim 98, wherein part of a lobe, an entire lobe, or an entire lobe plus additional surrounding tissue is severed and removed from the selected region.

101. The method of claim 96, wherein the cutting tool is energized at least one of before and during said advancing to facilitate tissue penetration.

102. The method of claim 96, further comprising, after said advancing, evaluating the distance and angle of the guide with respect to the lesion.

103. The method of claim 102, wherein the distal tips of the guide lumens are extendable from a distal end of a tubular shaft.

104. The method of claim 103, further comprising, after said evaluating, repositioning the distal end of the tubular shaft relative to the lesion to facilitate extension of the distal tips of the guide lumens from the tubular shaft to a predetermined position with respect to the lesion.

105. The method of claim 104, further comprising, after said repositioning, extending the distal tips of the guide lumens from the tubular shaft to the predetermined position.

106. The method of claim 105, wherein the cutting tool is energized before or during said extending the distal tips of the guide lumens to facilitate tissue penetration.

107. The method of claim 104, wherein the predetermined position is one of distal and proximal to the lesion with respect to the incision.

108. The method of claim 96, further comprising energizing a tissue penetration means of a tubular shaft containing the guide at least one of before and during said advancing to facilitate tissue penetration.

109. The method of claim 96, wherein said extending comprises extending the cutting loop through a window near a distal end of the tubular shaft.

110. The method of claim 96, wherein said extending comprises moving the distal tips relative to each other to selectively narrow or widen the cutting loop.

111. The method of claim 96, wherein the distal segments maintain a generally fixed distance therebetween.

112. The method of claim 96, further comprising energizing the cutting tool at least one of before and during said extending.

113. The method of claim 96, wherein said moving comprises at least one of withdrawing and advancing the guide in a direction along the guide axis.

114. The method of claim 96, further comprising, at least one of during and after said moving, marking the severed tissue.

115. The method of claim 96, further comprising, at least one of during and after said moving, capturing the severed tissue.

116. The method of claim 115, wherein said capturing the severed tissue comprises extending a collection bag from at least one of the guide and a tubular shaft containing the guide.

117. A method for removing a lesion from a patient, comprising:

locating the lesion to be severed and removed from within a selected region of the patient;

inserting a guide through an incision, the guide comprising two co-linear, co-extensive guide lumens longitudinally extending from a proximal region to a distal terminus along a guide axis, wherein the guide lumens have co-extensive distal segments terminating in distal tips and deformable regions immediately proximal to the distal segments, said deformable regions facilitate in changing the direction of each distal segment with respect to the guide axis;

advancing the guide into the selected region to position the distal terminus of the guide to a predetermined position with respect to the lesion;

extending a cutting tool contained within the guide from the distal tips of the two guide lumens to form a cutting loop, said cutting loop having a loop extension axis defined by the direction in which the cutting loop extends; and

moving the cutting loop using the guide along the guide axis to sever tissue containing the lesion from the selected region.

118. The method of claim 117, further comprising varying the direction of at least one of the distal segments with respect to the guide axis, thereby changing the angle between the loop extension axis and the guide axis, whereby the cutting loop is repositioned with respect to the guide axis.

119. The method of claim 117, wherein the distal segments maintain a generally fixed distance therebetween.

120. The method of claim 117, further comprising, prior to or during said extending, varying the distance between the distal segments to selectively widen or narrow the cutting loop.

121. A method for removing a lesion from a patient, comprising:

locating a lesion to be severed and removed from within a selected region of the patient;

inserting a guide into the selected region through an incision, the guide comprising a guide lumen longitudinally extending from a proximal region to a distal terminus along a guide axis, wherein the guide lumen has a distal segment terminating in a distal tip;

advancing the guide into the selected region to position the distal terminus of the guide to a predetermined position with respect to the lesion;

extending a cutting tool having a fixed end at least partially contained within the guide lumen when in a stored configuration and extendable from the distal tip thereof to form a cutting loop, said cutting loop having a loop extension axis defined by the direction in which the cutting loop extends; and

moving the cutting loop using the guide along the guide axis to sever tissue containing the lesion from the selected region.

122. The method of claim 121, further comprising changing the direction of the distal segment of the guide lumen with respect to the guide axis, wherein the guide lumen has a deformable region immediately proximal to the distal segment, the deformable region facilitates in changing the direction of the distal segment.

123. The method of claim 121, further comprising, before said extending, changing the distance between the distal segment and the fixed end to selectively widen or narrow the loop, wherein the fixed end is attached to a tubular shaft containing the guide.